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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,775	06/30/2003	John C. Hill	FLORA.1300	1915

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/611,775	HILL ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 01/16/2009.

Claims 1-34 have been canceled.

Claims 35-40 are pending and included in the prosecution.

Upon further review and reconsideration, a new office action on the merit has been issued as follows:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 35-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Upon further review, the amendment filed 08/09/2006 was found to introduce new matter. The amendment added new claims 35-

40 that recite: “at least more than about 10 weight percent long carbon chain prior to hydrolysis.” Additionally, the amendment filed 08/05/2008 introduced new matter by reciting “lipid comprises at least more than about 10 weight percent long carbon chain prior to hydrolysis”. Recourse to the specification, nowhere applicants disclosed lipid or any material comprises “at least more than 10% long carbon chain prior to hydrolysis”.

3. Claims 35-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for composition comprising at least 10% polar hydrophilic salts (saponifiable) and at least 6% non-polar lipophilic (unsaponifiable) of jojoba oil at a ratio of 55:45, does not reasonably provide enablement for composition comprises the products of hydrolysis of a any other lipids including animal and fungal derived oils. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir.1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the

examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is method of providing a composition for topical application, said method comprising the step of neutralizing gelling agent with an effective amount of composition comprises polar hydrophilic salts and non-polar unsaponifiables, wherein said polar hydrophilic salts and said non-polar unsaponifiables comprise the products of hydrolysis of a lipid comprising jojoba oil, wherein said lipid comprises at least more than about 10 weight percent long carbon chain material prior to hydrolysis. The specification disclosed jojoba oil hydrolysis and disclosed specific percentage and ratio of saponifiable and non-saponifiable content. Nowhere in the specification applicants had disclosed hydrolysis of other lipid.

The breadth of the claims: The claims are very broad. The claims encompass any hydrolyzed lipid composition that mixed with or comprises jojoba oil. Claims 36 and 39 recite that the lipid that comprises jojoba oil selected from “oil from fungi, shark liver oil, and dog fish oil” which are not plant source, and no way to contain jojoba oil.

The state of the prior art: The state of the art does not recognize composition comprises the products of hydrolysis of jojoba oil comprising at least 10% polar hydrophilic salts and at least 6% non-polar lipophilic unsaponifiables at ratio of 55:45, however, the prior art recognized cosmetic composition comprising unsaponifiable and saponifiable fractions of oils including jojoba oil, see US FR 2471775.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The specification provides no guidance, in the way written description, on hydrolyzed lipid that provides composition comprising polar hydrophilic salts and non-polar unsaponifiables. The specification provided guidance regarding hydrolyzed jojoba oil comprising at least 10% polar hydrophilic salts and at least 6% non-polar lipophilic unsaponifiables in the ratio of 55:45. It is not obvious from the disclosure of hydrolyzed jojoba oil if the other hydrolyzed lipids including those of plant, animal, and fungal origin will provide the same hydrolysis products and work in the same way regarding increasing substantive skin benefit. In page 14, lines 6-14, applicants disclosed that: "Refined jojoba oil contains various proportions of long chain diunsaturated esters. Hydrolysates of refined jojoba oil are nearly a 55:45 mixture of polar hydrophilic long chain salts (alkali salts) and relatively non-polar lipophilic materials (fatty alcohols). The lipophilic fraction is the unsaponifiable materials according to the definition used in this document. The carbon chain lengths of both of these jojoba Hydrolysates include and vary from C_{18} to C_{24} and have ω-9 double bonds as part of each molecule. It has been found that the combination of saponifiable and unsaponifiable fractions of the Hydrolysates according to the present invention has properties that aid in the formulation of cosmetic, pharmaceutical, and other compositions". Applicants admit that the starting material will affect the product of hydrolysis in terms of saponifiable and non-saponifiable contents, page 13, lines 26-29 of the present disclosure. It is not clear from the specification what are the hydrolysis content of any other lipids, the ratio of saponifiable and non-saponifiable, and their effects. *In re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA

1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al*. (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of guidance from the specification and from the prior art with regard to substantive effect of the composition comprising saponifiable and non saponifiable fractions of lipid makes practicing the claimed invention unpredictable in the terms of lipid providing the desired skin effect.

The presence or absence of working examples: The specification exemplifies only hydrolyzed jojoba oils comprising specific ratio of its content of saponifiable and non-saponifiable. Therefore, the specification has enabled hydrolyzed jojoba oils comprising specific concentration and ratio of 55:45 saponifiable to non-saponifiable.

The quantity of experimentation necessary: Therefor, the practitioner would turn to trial and error experimentation to practice the instant method of making composition of hydrolyzed lipid comprising specific ratio of its content of saponifiable and non-saponifiable without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 35-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "at least more than about" renders the claim indefinite as it does not set forth the metes and bounds of the claims. The specification does not define the expression. Additionally, the term “at least more than 10%” does not encompass values below 10%, while the term “about” encompasses values below 10%. The terms are not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably recognize of the scope of the invention.

Additionally, the claims are confusing because claims 35 and 38 recite lipid comprising jojoba oil that is implied to be derived from plant *Simmondsia chinensis*, and claims 36 and 39 recite that the lipid of claims 35 and 38, respectively, comprises material selected from shark-liver oil, dog fish oil and oils from fungi. How lipid comprising jojoba oil will be derived from animal or fungal origin?

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 35-40 are rejected under 35 U.S.C. 103(a) as being obvious over FR 2471775 ('775) combined with US 6,280,746 ('746).

The applied reference ('764) has a common assignee and one common inventor with the instant application. Based upon the earlier effective U.S. filing date of the

reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

FR '775 teaches cosmetic composition comprising mixture of jojoba oil and sunflower oil, and from 20-40% unsaponifiables oils fractions (page 4, 3rd paragraph). The unsaponifiable fraction includes residual part of saponifiable components and unsaponifiable fraction, with the unsaponifiable ingredients is greater than 40% (paragraph bridging pages 4 and 5). The cosmetic composition can be in the form of gel (last paragraph of page 5). Examples 3-5 and 7 showed composition comprising gelling agent Caropol 940, which is an acidic gelling agent.

Although FR '775 teaches composition comprising saponifiable and unsaponifiables fractions obtained from vegetable oils and suggested jojoba oil, however, the reference does not explicitly teach hydrolysis of the oil.

US '746 teaches cosmetic composition comprising jojoba oil ester (abstract). When applied to the skin, the cosmetic composition comprising jojoba oil ester prevents and retains natural moisture level of the skin (col.8, lines 18-24). The composition comprising jojoba oil esters from the trade name Floraesters-15, 20, 30, 60 70 (col.8, lines 35-40). The reference disclosed that jojoba esters are catalyzed, i.e. hydrolyzed, using alkali metal hydroxide, as applicants had done (col.3, lines 53-60). The reference disclosed gel (example 2). The Floraester disclosed by the reference are expected to have polar hydrophilic salt and non-polar unsaponifiable fractions of jojoba oil, and expected to comprise more than 10% long chain carbon material prior to hydrolysis. Hydrolyzed jojoba esters are produced using potassium hydroxide, and therefore they are alkaline and expected to be capable to neutralize acidic gelling agent.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide gel cosmetic composition comprising saponifiable and unsaponifiable oil fractions as disclosed by FR '775, and select jojoba oil suggested by the reference and further use hydrolyzed jojoba oil esters as disclosed by US '746. One would have been motivated to do so because US '746 teaches that cosmetic composition comprising hydrolyzed jojoba ester when applied to the skin prevents and retains natural moisture level of the skin. One would have reasonably expected formulating gel cosmetic composition comprising hydrolyzed jojoba oil comprising

saponifiable and unsaponifiable fractions wherein the composition prevents and retains natural moisture level on application to the skin.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 35-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 7,435,424 ('424) in view of US 6,280,746 ('746). The present claims and the patented claims are directed to composition comprising saponifiable and nonsaponifiable fraction of jojoba oil. The method of neutralization is encompassed and disclosed by the US '424. However, US '424 does not claim gel composition.

US '746 teaches gel cosmetic composition comprising hydrolyzed jojoba oil esters that when applied to the skin prevents and retains natural moisture level of the skin.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising saponifiable and nonsaponifiable fraction of jojoba oil, and provide the composition in form of gel as disclosed by US '746. One would have been motivated to do so because US '746 teaches that cosmetic composition comprising hydrolyzed jojoba ester can be provide in a gel formulation that when applied to the skin prevents and retains natural moisture level of the skin. One would have reasonably expected formulating gel cosmetic composition comprising hydrolyzed jojoba oil comprising saponifiable and unsaponifiable fractions wherein the composition prevents and retains natural moisture level of the skin on application to the skin.

Response to Arguments and 37 C.F.R. §l.132 Declaration

12. Applicant's arguments with respect to claims 35-40 and declaration under 37 C.F.R. §l.132 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-

0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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